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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,214

09/21/2005

Ivan Salgo

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03/17/2010

PHILIPS INTELLECTUAL PROPERTY & STANDARDS

P.O. BOX 3001

Briarcliff Manor, NY 10510-8001

EXAMINER

CARTER, AARON W

ART UNIT

PAPER NUMBER

2624

MAIL DATE

DELIVERY MODE

03/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,214	Applicant(s) SALGO ET AL.	
	Examiner AARON W. CARTER	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-9 and 11-13 is/are allowed.
- 6) ☒ Claim(s) 1-5, 10 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to papers filed on 10/26/09.

Response to Amendment

2. In response to applicant's amendment received on 10/26/09, all requested changes to the claims have been entered. Claims 1-19 are currently pending.

Response to Arguments

Applicant's arguments filed 10/26/09 have been fully considered but they are not persuasive.

3. Regarding claims 1, 14 and 15, Applicants argue that the prior art of Gilboa et al. does not teach or fairly suggest producing a real time three dimensional ultrasonic image into which information from an invasive medical device has been merged.

The Examiner disagrees and the rejection is maintained. The prior art of Gilboa et al. discloses merging ultrasonic images with information from an invasive medical device in "Example 1" disclosed in column 8, line 49 - column 10, line 43. Gilboa then discloses in "Example 2", column 10, lines 45-56, that example 1 may be performed using real time 3D ultrasonic images.

Art Unit: 2624

4. Regarding claims 10, 18 and 19, Applicant's argue that the prior art of Strommer et al. does not teach or fairly suggest the use real-time images.

The prior Strommer et al. discloses the use of real-time ECG data with saved ultrasound images to produce a real-time ultrasound image representation of the organ. The displayed ultrasound representation maybe in 3D, merged with real-time information from an invasive medical device and include the ECG trace data. Strommer et al. does not acquire real-time ultrasound images as required by the limitations of the independent claims, however it can be said that a real-time ultrasonic image representation is displayed since ECG data used is acquired in real time. Furthermore, Strommer et al. is relied on to provide evidence that is would have been of the obvious to incorporate ECG trace data on the display disclosed by Gilboa et al. which does acquire and displays real-time 3D ultrasound images.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by USPN 6,996,430 to Gilboa et al. ("Gilboa").

Art Unit: 2624

As to claim 1, Gilboa discloses a method of observing the operation of an invasive medical device comprising:

Operating an invasive medical device from an invasive medical device system to perform an activity within a body (*Fig. 1, element 170 and column 7, line 51 - column 8, line 17*);

Operating an ultrasonic diagnostic imaging system to observe the invasive medical device by means of a real time three dimensional ultrasonic image (*column 10, lines 47-56*);

Producing information with the invasive medical device system having coordinate information relating to the activity (*column 9, lines 17-20 and column 10, lines 14-17*); and

Merging information from the invasive medical device system into the real time three dimensional ultrasonic image at a location in the ultrasonic image data which is determined from the coordinate information (*column 10, lines 14-17*).

As to claim 2, Gilboa discloses the method of claim 1, wherein the invasive medical device includes a position sensor; and

Wherein producing information with the invasive medical device system comprises producing coordinate information in response to signals received from the position sensor (*Fig. 1, element 138 and column 9, lines 17-20*).

As to claim 3, Gilboa discloses the method of claim 2, wherein the position sensor comprises a receiver which receives signals in an acoustic, optical radio frequency, or electromagnetic spectrum (*column 8, lines 56-67*).

Art Unit: 2624

As to claim 4, Gilboa discloses the method of claim 2, wherein the position sensor comprises a transmitter which transmit signals in the acoustic, optical, radio frequency or electromagnetic spectrum (*column 8, lines 56-67*).

As to claim 5, Gilboa discloses the method of claim 1, wherein merging information further comprises merging locational information into the real time three dimensional ultrasonic image at locations where activity of the invasive medical device has been performed (*column 10, lines 14-17*).

As to claim 14, Gilboa discloses a method of guiding the placement of an invasive medical device with a three dimensional ultrasonic imaging and invasive medical device operating system comprising:

Operating an invasive medical device by means of an interventional device subsystem to perform an activity within a body (*Fig. 1, element 170 and column 7, line 51 - column 8, line 17*);

Acquiring ultrasonic echo information by means of an ultrasonic imaging subsystem from a volumetric region containing the invasive medical device (*column 10, lines 47-56*);

Producing information from the invasive medical device having coordinate information relating to the activity (*column 9, lines 17-20 and column 10, lines 14-17*);

Producing a real time three dimensional ultrasonic image with spatially coordinated invasive medical device activity information from the ultrasonic echo information and the information from the invasive medical device (*column 10, lines 14-17*); and

Art Unit: 2624

Displaying the real time three dimensional ultrasonic image with spatially coordinated invasive medical device activity information on an image display (*column 10, lines 14-17*).

As to claim 15, Gilboa discloses an ultrasonic surgical guidance imaging system which acts to observe the operation of an invasive medical device comprising:

An ultrasonic probe including an array transducer which steers ultrasonic beams over a volumetric region for image guidance of the operation of an invasive medical device (*Fig. 1, element 120 and column 10, lines 47-56*);

An ultrasound acquisition subsystem coupled to the ultrasonic probe (*Fig. 1, element 125 and column 10, lines 47-56*);

An invasive medical device (*Fig. 1, element 170*);

An interventional device subsystem coupled to the invasive medical device (*Fig. 1, element 130*);

A 3D image processor coupled to the ultrasound acquisition subsystem and the interventional device subsystem which operates to produce 3D ultrasound images containing locational information of the invasive medical device in real time (*Fig. 1, element 140 and column 10, lines 14-17*); and

An image display coupled to the 3D image processor (*Fig. 1, elements 160 and 162*).

As to claim 16, Gilboa discloses the ultrasonic surgical guidance imaging system of claim 15, wherein the invasive medical device further includes a position sensor (*Fig. 1, element 138*);

Art Unit: 2624

and wherein the interventional device subsystem further includes a device position measurement subsystem coupled to the position sensor (*Fig. 1, element 130*).

As to claim 17, Gilboa discloses the ultrasonic surgical guidance imaging system of claim 16, wherein the 3D image processor is further responsive to locational signals produced by the device position measurement subsystem (*Fig. 1, element 140 and column 10, lines 14-17*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 10, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa in view of USPN 2002/0049375 of Strommer et al. (“Strommer”) (already of record).

As to claim 10, Gilboa discloses the method of claim 1.

Gilboa does not disclose expressly acquiring ECG data; and further comprising displaying both the real time three dimensional ultrasonic image containing merged information from the invasive medical device system and an ECG trace.

Art Unit: 2624

However, Strommer discloses displaying both the real time ultrasonic image containing merged information from the invasive medical device system and an ECG trace (*Fig. 1, paragraphs 41, 116, 117, 167*).

Gilboa & Strommer are combinable because they are from the same art of image processing.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the process of displaying both a real time ultrasonic image and ECG trace, as taught by Strommer, with the method of observing the operation of an invasive medical device disclosed by Gilboa.

The suggestion/motivation for doing so would have been to provide a graphical user interface comprising image data as well ECG data that can be monitored which enhances diagnostics (*Strommer, paragraph 3 and 41*).

Therefore, it would have been obvious to combine Gilboa with Strommer to obtain the invention as specified in claim 10.

As to claim 18, please refer to the rejection of claim 10 above.

As to claim 19, please refer to the rejection of claim 10 above.

Allowable Subject Matter

7. Claims 6-9 and 11-13 are allowed.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON W. CARTER whose telephone number is (571)272-7445. The examiner can normally be reached on 9am - 5:30 pm (Mon. - Fri.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on (571) 272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 2624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron W Carter/

Primary Examiner, Art Unit 2624